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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/660,256 | 09/11/2003 | Arthur Ramazanov | 4287/1M315US1 | 5361 |
| 7278 | 7590 | 06/12/2006 | EXAMINER | |
| DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257 | | | SPIVACK, PHYLLIS G | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |
| DATE MAILED: 06/12/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,256

Applicant(s)

RAMAZANOV ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-9 and 12 is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3-17-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment filed March 17, 2006 is acknowledged. New claims 12 and 13 are presented. Claims 10 and 11 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Claims 1-9, 12 and 13 are under consideration.

An Information Disclosure Statement filed March 17, 2006 is further acknowledged and has been reviewed.

A Declaration of Zakir Ramazanov under 37 CFR 1.132 is further acknowledged. Amendments to the Abstract are noted.

In the last Office Action claims 1-9 were rejected under 35 U.S.C. 103 as being unpatentable over both Igarashi et al., Biosci., Biotech., Biochem., and Yamahara, J., JP2002187845 (abstract).

Igarashi teaches the administration of taxifolin, the compound depicted at the bottom of page 513, where R = H, which is dihydroquercetin, to reduce total body weight and fat mass. Yamahara teaches the use of saccharides from the buds of the *Aralia elata* plant as an antiobesity drug.

Upon reconsideration, Igarashi teaches no significant impact on body weight. The Ramazanov Declaration teaches by the HPLC comparative analysis depicted in Exhibits B, C and D, that the saponin compositions of *Aralia* root bark and bud material are clearly different. Accordingly, the rejection of record under 35 U.S.C. 103 is withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Hong et al., U.S. Patent 6,827,950, and Babenkova et al., Vestnik oftalmologii (abstract).

Hong teaches pharmaceutical compositions comprising *Aralia* extracts and a therapeutic agent in the treatment of cataracts. See the Abstract. It would have been reasonable to expect the "extract" to consist of both root-derived and bud-derived aralosides according to the disclosure. Due to its antioxidative activity, Babenkova teaches the administration of dihydroquercetin in the treatment of eye diseases.

Therefore, in view of the teachings of Hong and Babenkova, one skilled in the ophthalmology art would have been motivated to prepare a pharmaceutical composition comprising both dihydroquercetin and *Aralia* extracts to treat ocular diseases that involve the lens of the eye. Such would have been obvious in the absence of evidence to the contrary because the teachings of Hong are not limited to extracts of *Aralia* from any one source. Further, quercetin, a component in the extract of *Aralia*, is described as having excellent anti-oxidation properties and would be considered helpful in inhibiting the generation of cataracts. See the top of column 12.

The selections of optimal concentrations or ratios of dihydroquercetins and aralosides are parameters well within the purview of the skilled artisan through no more than routine experimentation.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel can be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 8, 2006

Phyllis G. Spivack



PHYLLIS SPIVACK
PATENT EXAMINER